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UNITED STATES PATENT APPLICATION

FOR

CATHETER INCLUDING TEXTURED INTERFACE

by

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CATHETER INCLUDING TEXTURED INTERFACE

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to the use of catheters for the introduction of fluids directly into the blood stream and claims benefit of prior filed copending Provisional Application No. 60/156,300, filed September 24, 1999.

Background of the Invention

Medical catheters are commonly used for the introduction of fluids into the bloodstream during medical procedures. Such catheters are available commercially in numerous embodiments designed specifically for such various medical procedures. These catheters are commonly inserted into the blood vessel of the patient through the use of an introducer or a needle and then held in place either by tape or by suturing the catheter to the blood vessel or surrounding tissue.

One problem commonly encountered in such procedures particularly where the catheter is inserted directly into the blood vessel and particularly during pediatric surgery is that the portion of the catheter which interfaces with the blood vessel is smooth, most generally comprised of plastic such that when an attempt is made to secure the catheter within the vessel, most commonly by tying a suture around the interfacing portion of the catheter, the pressure created by tightening of the suture causes the suture to eject or squirt from the blood vessel before it can be secured thereon. As a result, the possibility of contamination of the sterile catheter exists, not to mention the loss of valuable and expensive surgical time. A need therefore exists for a catheter which includes a textured interface so as to provide a frictional component to retain the catheter within the blood vessel while it is secured therein.

In addition to the use of catheters, intravenous stents (I.V.'s) are almost universally inserted into the dorsal vein of the hand when a person is admitted to a hospital or during the administration of a medical procedure. These intravenous stents, as well as many types of catheters, are designed to be maintained in the patient's body for a period of time which

could exceed several days, weeks, or longer. In such situations the patient, if able, will be required to perform routine daily activities with the I.V. stent or catheter inserted in his or her body. Such routine activity and movement causes the portion of the I.V. or catheter which interfaces with the skin or blood vessel to move or migrate therein. A known concern is that such movement of the interface within the skin tissue or blood vessel may allow the introduction of infection causing organisms to enter the body or blood vessel. Such organisms may potentially result in a serious bodily infection. A need therefor exists for an I.V. stent and catheter which includes a textured interface to allow secure placement of the I.V. or catheter within the patient's skin tissue or blood vessel.

Central venous catheters have unique requirements to be maintained in a fixed position in the body to avoid migration and infection. Migration may produce serious vascular perforations, complications, and catheter infection produces sepsis both of which may be fatal complications.

Both complications will be reduced by improved fixation of the catheter and natural tissue attachment to the textured surfaces. Pediatric patients have especially difficult fixation problems due to larger catheter size to body size ratios and inability of the patient to cooperate in catheter long term care.

In addition, as the distance the catheter (or I.V.) body interface is positioned or secured from the situs of penetration into the patient's skin tissue/blood vessel increases, an increase in the resultant migration thereof is realized. As stated, the result of increased migration of the catheter (or I.V.) body interface is an increased risk of infection. A need, therefore, exists for a catheter or I.V. which is textured to restrain the catheter body interface within or adjacent the situs of penetration.

SUMMARY OF THE INVENTION

The present invention is a catheter including a body for insertion into a blood vessel of a medical patient. The body includes an interface thereon which is the portion of the body that is inserted into the blood vessel and is in contact therewith. A cannula may extend from the interface. The interface includes texture on its exterior surface such that when the body is inserted into the blood vessel, it can be secured therein without being ejected from the blood vessel during the process of securing the body within the blood vessel. As such, the textured interface provides sufficient frictional contact with the patient's skin or blood vessel so as to grip or retain the body therein while it is being tied or sutured in place. The texture thereby provides an increased surface area which is obtained by scoring or molding indentations within and along the length of the interface to provide such texture. Examples of suitable texture include diagonal cross-hatching or knurling, threading, concentric indentations cut along its length of either a fine depth and spacing or a coarse depth and spacing thereby providing ridges or concentric "donut" shapes along the length of the interface, or a plurality of cells or ridges positioned along the exterior surface of the interface. It is desirable that such texture provides increased surface area so as to achieve frictional contact between the interface and the blood vessel without causing damage to the blood vessel or surrounding tissue.

The texture of the present invention may also be used in alternate embodiment catheters which include a body having an interface thereon, a lumen for the introduction of liquids through the catheter, and wire guide obturator. In such an embodiment, the catheter is typically introduced through the skin and into the blood vessel such that the interface of the body is in direct contact with the skin tissue of the patient while the cannula pierces therethrough into and generally along the blood vessel. Catheters of this type are generally installed for periods of several days, weeks or longer for the long term introduction of fluids directly into the blood vessel. In such cases, the textured interface of the catheter body restricts movement of the catheter body within the skin tissue such that the tendency of the

piercing wound to heal allows the skin cells (microplast) to grow in the texture thereby securing the catheter body from migration. In this way, the textured interface reduces and may eliminate the introduction of bacteria or fungi which have the potential of causing infection within the patient's body. A portion of the cannula may also be textured to further assist in securing the catheter from migration. It has been found that the catheter body should be fixed at the point of entry into the patient's body, as according to the present invention.

In addition, intravenous stents almost universally inserted into a patient's body during medical procedures may include a textured interface portion for the purpose of securing the stent within the patient's vein thereby also restricting the possibility of the introduction of infection causing organisms into the body or blood stream of the patient.

It is therefore an object of the present invention to include a catheter having a body including a portion which interfaces with the skin tissue or blood vessel of a patient during medical treatment wherein the interface is textured.

It is another object of the present invention to texture the interface of a catheter, and specifically an arterial or venous catheter to retain the catheter therein while it is secured in the patient's blood vessel.

It is still another object of the invention to provide an intravenous stent with a textured interface thereon.

A yet further object of the present invention is to provide a catheter or I.V. with a textured body interface thereby restraining this body interface within the situs of penetration into the patient's skin tissue/blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a central venous catheter which includes a textured interface of the present invention.

FIGURE 2 is the central venous catheter of FIG. 1 wherein the knurled textured interface is depicted piercing and in contact with the skin of the patient.

FIGURE 3 is the central venous catheter of FIG. 1 configured with an alternate textured configuration including concentric rings cut in the length of the interface.

FIGURE 4 is the central venous catheter of FIG. 1 configured with a second alternate textured configuration concentric rings having deeper channels than the first alternate textured configuration of FIG. 3 .

FIGURE 5 is the central venous catheter of FIG. 1 configured with a third alternate textured configuration including integral raised cells or bumps on the interface.

FIGURE 6 is the central venous catheter of FIG. 1 configured with a fourth alternate texture configuration including cells or bumps which are smaller than the cells or bumps of the third textured configuration of FIG. 5.

FIGURE 7 depicts a plan view of a peripherally inserted central venous catheter (PICC) including textured interface.

FIGURE 8 is a plan view of an intravenous stent which includes the textured interface of the present invention.

FIGURE 9 is an exploded view of the intravenous catheter of FIG. 8 wherein the stent portion includes the textured interface of the present invention.

FIGURE 10 is a plan view of a catheter inducer which includes the textured interface of the present invention.

FIGURE 11 is a view of a alternate embodiment catheter inducer which includes the textured interface of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGURE 1 depicts a central venous catheter, and in particular, a peripherally inserted central venous catheter body **10** including lumen **12**, wings **14** and **16**, interface **18**, and wire guide obturator **20** extending therefrom. Pursuant to the present invention, interface **18** includes a texture thereon such that when catheter **10** is inserted into a patient, the textured portion **22** of interface **18** is in contact with the patient's skin in order to keep catheter body **10** stationery therein. Referring more particularly to FIG. 2, where catheter body **10** is shown inserted through the skin **24** of a patient and into a vein **26**. As such, cannula **20** extends from lumen **12** of catheter body **10** and into skin **24** and into vein **26**. Interface **18** is the portion of catheter body **10** between cannula **20** and lumen **12**. Interface **18** extends into the skin **24** of the patient. Texture **22** on interface **18** and or a portion of the first end of cannula **20** creates frictional contact between interface **18** (and cannula **20**) of catheter body **10** and skin **24**. Such frictional contact helps prevent catheter body **10** from moving or migrating within skin **24** or becoming dislodged therefrom.

Catheter body **10** is secured in place within the patient's body at the point of entry of interface **18** and cannula **20**.

An additional important function of texture **22** is that the skin **24** (microplast) surrounding interface **18** will grow in an attempt to close or heal the hole (puncture) through which interface **18** and cannula **20** are inserted such that the cells will grow into engagement with the greater surface area of the interface caused by the texture in an attempt to close the puncture wound caused when the catheter was inserted. This interface between the cells of skin **24** and texture **22** of interface **18** will help deter interface **18** from moving in and out of skin **24** when the patient moves through activity. In this way, the possibility of infection causing germs from entering the puncture wound through skin **24** and the blood stream within vein **26** from the portion of interface **18** extending outside of skin **24** is greatly reduced. Such reduction in the possibility of the introduction of bacteria or fungus into the body is significant in the reduction of serious infection possibilities inherent in the use of the

venous catheter. This infection risk is generally heightened by the typically weakened state of the patient's immune system as a result of the medical condition necessitating the use of the catheter.

The style of texture **22** in the preferred embodiment of FIG. 1 is a cross-hatching or knurling wherein lines are cut into the surface of interface **18** in a diagonal fashion along the annular, semi-cylindrical circumference of interface **18**. The diagonal lines are cut such that they cross thereby forming discreet square or most commonly diagonal patterns **28**. In that the diagonal lines are cut into the surface of interface **18**, their crossing thereby defines discreet pattern **28** appearing raised above the circumference of interface **18**. Each such discreet pattern **28** is separated from the next by the cross-hatched diagonal indentions. The particular geometric shape of individual pattern **28** is determined by the angle of the diagonal line cut in the surface of interface **18**. For the purpose of exemplification, 500 microns is a suitable depth of texture **22**, however, other depths are contemplated depending on the application.

Although texture **22** has been defined herein as being formed by cutting diagonal lines in the surface of interface **18**, it is understood that other methods of manufacture are contemplated such as by injection molding the texture into the surface of interface **18** or such other manufacturing processes known in the art.

In addition, it is understood that individual configuration **28** could be defined by other types of indentions in interface **18** such as curved lines or perpendicular lines. Although the particular geometric design of FIG. 1 is preferred.

Referring next to FIG. 3, a first alternate embodiment texture is disclosed. Interface **32** of catheter **30** includes first alternate embodiment texture **34**. First alternate texture **34** is defined by a series of concentric rings cut in the exterior circumference of interface **32**. As with the preferred embodiment, the annular rings, as exemplified by ring **36** may be either cut in the surface of interface **32** or molded therein during the manufacture of catheter **30**.

Annular rings **36** and **38** of texture **34** bound and define a discreet raised annular slice

of interface **32**. Each independent slice **37** may have equal diameters or may increase or reduce in diameter along the length of interface **32** as desired.

Catheter **30** may be substituted for catheter **10** in FIG. 2 such that wire guide obturator **39** pierces skin **24** and extends into vein **26** such that interface **32** engages skin **24** at the surface thereof and provides frictional contact therein. Texture **34** further provides the protection against infection as described above.

FIG. 4 depicts a central venous catheter **40** including a second alternate embodiment texture **44** along interface **42**. In this second alternate embodiment texture **42**, the concentric rings, as exemplified by rings **46** and **48**, are deeper in interface **42** defining a larger, more donut-shaped individual configuration as exemplified by configuration **47**. Each individual "donut-shaped" texture configuration may be of equal size or increase or decrease in diameter along the length of interface **42** as desired for the required application or efficiency. Additionally, as stated above, texture **44** may be created in interface **42** at the time of its manufacture, typically by molding, or thereafter by a machine process.

Second alternate embodiment catheter **40** may be substituted for catheter **10** of FIG. 2 such that wire guide obturator **49** pierces skin **24** and enters vein **26** such that texture **44** pierces skin **24** in contact thereof.

Referring next to FIG. 5, wherein a central venous catheter **50** includes a third alternate embodiment texture **54** is disclose on interface **52**. Third alternate texture embodiment texture **54** includes a series of cells or ridges **55-57** which extend above the cylindrical circumference of interface **52**. Cells, or bumps, **55-57** may be formed in any known manner, however, it is believed that forming thereof during forming of interface **52** is the most efficient method. It is preferred that cells **55-57** be formed so as to provide a smooth texture and thereby rounded so as to minimize damage to the patient's tissue during use thereof. However, more pointed cells are contemplated in the invent that superior frictional capabilities of texture **54** are necessary.

Catheter **50** may be substituted for catheter **10** in FIG. 2 such that interface **52**

extends into skin **24** and is in frictional contact therewith.

Venous catheter **60** of FIG. 6 includes a plurality of smaller bumps, exemplified by bump **66** on interface **62**. As can be seen, bump **66** is smaller than bump **55** of FIG. 5. As such, texture **64** of catheter **60** of FIG. 6 may be desirable for applications where less aggressive frictional contact between interface **62** and the surrounding patient's tissue is appropriate. The number of bumps such as bump **66** may be varied also as necessary. Bumps, such as bump **66**, may be rounded or may have point thereon as desired for suitable applications.

Catheter **60** including texture **64** may be manufactured according to any suitable process. Catheter **60** may also be substituted for catheter **10** in FIG. 2 such that texture **64** of interface **62** is in contact with skin **24** upon insertion of catheter **60** through skin **24** into vein **26**.

FIG. 7 depicts a peripherally inserted central venous catheter (PICC) **70** wherein interface **72** includes texture **74** thereon. As can be seen, the portion of wire guide obturator **76** adjoining interface **72** may also be textured to allow greater frictional interaction with the surrounding tissue. PICC **70** is configured in a dual lumen configuration including a larger lumen **78** and a small lumen **79**.

FIG. 8 depicts an assembled intravenous stent assembly **80**. Intravenous stent assembly **80** includes stent portion **82** and introducer/needle portion **84**. Intravenous stent assemblies such as assembly **80** are commonly used to provide intravenous access to a medical patient.

Taking FIG. 8 in combination with FIG. 9, intravenous stent assembly **80** includes stent portion **82**, introducer/needle portion **84** and plug **86**. In use, the assembled intravenous stent **80** (such as FIG. 8) is inserted into the patient's vein using needle **88**. Intravenous stent assembly such as **80** are commonly inserted into a vein in the top of the patient's hand, wherein needle **88** and surrounding cannula **90** are inserted into the vein. Once inserted, intravenous fluids may be added by injection through plug **86** or by the removal of plug **86**

and introduction through the hollow length of introducer **84**.

Most commonly, however, once inserted, introducer/needle portion **84** is removed thereby leaving stent **82** within the hand of the patient such that cannula **90** and interface **92** extend into the vein. Once introduced, stent **82** is typically taped or sutured in place through holes **94** and wings **96**. Introducer **92** of stent **82** includes texture **93** thereon. Texture **93** helps prevent stent **82** from being ejected by the vein. A portion of cannula **90** may also be textured, preferably adjacent introducer **92**. Texture **93** also reduces movement of introducer **92** and thereby stent **82** within the vein. Thus, a secure intravenous stent provided.

FIG. 10 depicts a catheter introducer assembly **100**. An introducer is also known in the art as a sheath or introducer sheath designed to allow controlled access to the body, minimize trauma to vein or artery and prevent excessive blood loss during a procedure. Introducers are available in many configurations to provide a sheath for introducing a catheter into the body.

Introducer **100** generally consists of two components, a sheath component **102** and a dilator component **104**. Dilator **104** is longer than sheath **102** and is comprised of a smooth, stiff tube with a taper at its distal end **105**. Dilator **104** fits within sheath **102**. Taper **105** when inserted into the patient acts to dilate the tissue in the skin and vein to allow the sheath to pass thereafter. Once the introducer is inserted into a vein through the skin and positioned therein, introducer **100** allows a catheter to be inserted into the vein.

Sheath **102** of introducer **100** includes texture **106** and **107** thereon in order to provide frictional engagement with the skin and vein when sheath **102** is inserted. Texture **106** also restricts sheath **102** from movement within the vein in order to reduce the possibility of introduction of infection causing bacteria and fungi. A hub **108** includes a valve therein to prevent blood from leaking from the vein. A catheter is generally inserted through hub **108**, sheath **102** and into the blood vessel to allow for the introduction of fluids therethrough. A side arm **110** terminating with a stop cock **112** is used to measure blood pressure and withdraw samples of blood for testing or otherwise.

FIG. 11 depicts introducer **120** for the insertion of guide wire **126** into a blood vessel to be followed by a catheter (such as PICC **70** of FIG. 7). Introducer body **120** is typically inserted directly into a severed vein such as in a angiogram procedure. Interface **122** of introducer body **120** includes texture **124** to provide frictional resistance while introducer body **120** is secured in the vein.

While the invention has been described with a certain degree of particularity, it is manifest that many changes may be made in the details of construction without departing from the spirit and scope of this disclosure. It is understood that the invention is not limited to the embodiment set forth herein for purposes of exemplification, but is to be limited only by the scope of the attached claim or claims, including the full range of equivalency to which each element thereof is entitled.